

Exploring issues in the development of Ayurvedic research methodology

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ABSTRACT

Research is the prime need of contemporary Ayurveda, but modern research on Ayurveda has not been very rewarding for Ayurveda itself. Much of it uses Ayurveda to extend modern bioscience. In contrast, Ayurveda needs research designed to test and validate its fundamental concepts as well as its treatments. In this context, if Ayurveda is to be truly explored and validated in all its aspects, scientific inputs should conform to Ayurveda's principles and philosophy. While its evidence base, established since antiquity, may need further verification, research should now focus on the Science of Ayurveda, rather than merely looking for new drugs based on Ayurveda herbals; in-depth research is needed on Ayurveda. Such research will require teamwork between scientists and vaidyas based on truth and trust. Ayurveda research methodology requires the 'whole system testing approach', global participation with protocols evolved through intense interface with modern science, regulatory reforms to eliminate barriers, and to be investigated 'as it is', using approaches adapted from its own basic principles.

Key words: Ayurveda, research, methodology.

INTRODUCTION

Ayurvedic researches undertaken during the last 50 years have not been very rewarding, except for the extremely useful exercise of literary research, which has at least made a few of the classical Ayurvedic texts accessible to contemporary readers and researchers.^[1-3] Similarly, a number of literary reviews published in recent years have helped create a conceptual interface between Ayurveda and modern science.^[4-15] However real laboratory-based new research is still awaited. Such a scientific stalemate warrants developing newer strategies for research in Ayurveda with appropriate methodology in keeping with the fundamental principles of Ayurveda-as-it-is, without distorting it to suit the application of modern research technology. In any research, the goal of research should not be compromised to suit the convenience of research methods. But unfortunately in Ayurvedic research, there has always been a reverse compromise, and in my perception this attitude

is the main reason for failures in this otherwise potentially most fruitful field of contemporary medical research. The so-called scientific research of several decades has helped neither Ayurveda nor modern medicine to any significant extent except in creating awareness. The present challenges are globalization of Ayurveda and industrialization of the Ayurvedic drug sector that needs standardization and quality assurance of in-use drugs, besides developing new drugs and formulations for more recent indications. That classical Ayurvedic formulations seem to be losing ground is evident from the drastic cuts in production and sale of classical drugs by most Ayurvedic drug companies. On the other hand, there is a strong need to explain fundamental principles of Ayurveda in a modern context. Further, we must also address the growing demand for an "evidence-base." Hence research is the prime need of contemporary Ayurveda. On the other hand, despite modern research in Ayurveda not having been very rewarding till now, it cannot be overemphasized that modern scientific inputs are unavoidable in this kind of research, the only rider being that, if Ayurveda is to be truly explored, such scientific inputs should conform to the principles and philosophy of Ayurveda.

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THE EARLY ATTEMPTS IN INDIA

Till now, the best research and development in Ayurveda has been the contribution of commentators on Samhitas

as well as scholarly works and translations of Ayurvedic classics in modern languages, such as the works of Yadavji Trikamji Acharya, Acharya Priya Vrata Sharma, GD Singhal, MS Valiathan, and several others. The credit for early attempts at modern drug-oriented research goes to individuals like RN Chopra, KN Udupa, and a few others besides,^[16–21] and to the establishment of Central Drug Research Institute, Regional Research Laboratory, Jorhat (RRLJ), Central Council for Research in Ayurveda and Sidha, and the Department of Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH), Govt of India. The identification of reserpine from *sarpagandha* as a therapeutic agent emerged as the big success story of the early 20th century, attracting large numbers of researchers; but within only a few years, this new phytochemical was subsequently withdrawn from the market as a drug because depression was a severe side effect, even though *sarpagandha* as a whole natural drug is free of the effect and continues to be in use even today.

This event proved to be a turning point in the field, shifting the research paradigm from active chemical constituents toward trials of the whole drug. More recently, the golden triangle project has been launched along the lines of the composite drug research scheme, which ended inconclusively during the late sixties, and the ongoing project on “Science Initiatives in Ayurveda” and the policy exercise for proposed Council for International Cooperation in ISM are still to take off.

DIMENSIONS OF CONTEMPORARY AYURVEDIC RESEARCH

The overall spectrum of contemporary research activities in Ayurveda includes literary and conceptual study, clinical and therapeutic research, and drug development research including drug standardization and new drug development. I have always been of the opinion that Ayurveda requires a two-pronged research enterprise:

1. Research in the science of Ayurveda,
2. Research on therapeutics of Ayurveda.

Earlier attempts were overwhelmed by drug research without any real breakthrough outputs. Now the paradigm seems to be shifting toward research on Science of Ayurveda as evidenced by Valiathan’s project on Science Initiatives in Ayurveda. My experience of collaborative research on Ayurveda during the last several decades prompts me to think that Ayurvedic research needs more collaboration with basic scientists than with professional medical doctors, because Ayurveda is more easily explainable in terms of basic sciences like physics, chemistry, and basic life sciences than in the language of conventional biology and medicine.

THE SPECTRUM OF EVIDENCE-BASE

One should not get the impression that Ayurvedic medicine has no evidence-base. Ever since antiquity, Ayurveda has been evidence conscious. All theory and practice of Ayurveda have been evidence-based, in its own time frame of course. Like any other branch of knowledge, Ayurveda may need to obtain new evidence from time to time. The critical scientific approach of Ayurveda is evident from its *Pramana Vijnan*. The ancient concept of evidence is based on fourfold testing. Classical methods are:

1. *Pratyaksa* (direct observation),
2. *Anumana* (inferential evidence),
3. *Aptopadesa* (scriptural evidence), and
4. *Yukti Pramana* (rationally planned experimental evidence).

The evidence-base of contemporary Ayurveda is conceived in several forms including:

1. Scriptural evidence and folklore claim,
2. Experience-based evidence, and
3. Long-standing traditional use and its mass acceptance.

But in spite of all this primary strength, one cannot deny the need to develop supportive new scientific evidence, without which contemporary Ayurveda will not be able to become a really global science, accessible to humanity at large, for their wider benefit. The World Health Organization has also expressed similar views.^[22–24]

The key issues in the assessment of therapeutic effects are clinical epidemiology for clinical research, standardization of diagnostic criteria, clinical trials to assess safety and efficacy, and systematic review of literature on clinical research. Cross-national evaluations using common protocols have been suggested by certain science activists from a global perspective, although that does not appear to me to be necessary. We have to weigh the evidence using systematic reviews and critical evaluation of information from completed studies. Research in practice settings and the reverse pharmacology approach seem to be correct strategies in traditional medicine research.

On the other hand, one cannot help noticing the conflicting attitudes of different regulatory agencies in different countries. According to the Committee on Herbal Medicinal Products regulation for registration of herbal products in Europe, “The rationale behind the actual registration procedure is to enable products which have been in long standing traditional use to be registered, because their safety and efficacy can be deduced from their long standing use. The long tradition of the medicinal product permits requirements for clinical trials to be waived, insofar as the efficacy of the

medicinal product is plausible on the basis of long-term use and experience. Preclinical tests do not seem necessary either, where the medicinal product on the basis of the information on its traditional use proves not to be harmful in specified conditions of use.”

This seems to be a laudably lenient stand, with which I personally agree, because Ayurveda in India has a superior status, many of its products and formulations having been in use for several hundred years, not merely decades. But I do not know whether this stand will be acceptable to the scientific community at large. However, one thing is sure: traditional medicine research does not require the same scientific rigor as conventional modern drug development programs.

EMERGING ISSUES AND THE SECTORIAL CONCERNS

In spite of many attempts at research in Ayurvedic therapeutics, no noteworthy outcome has emerged. Equally, no initiatives have so far been taken to study the core science of Ayurveda. Potentially valuable treasures in Ayurveda’s unique concepts and theories remain unexplored. Thus, research in Ayurveda during the last several decades has not produced any major breakthrough. Most so-called scientific studies have yielded negative results, warranting a serious reconsideration of the very approach of research and on-going research methodology. Many serious researchers now consider current research approaches to be inappropriate, and that a major paradigm shift to in-depth Ayurveda-oriented research on Ayurveda is needed.

Ongoing research is proceeding in such a way that it is of more value to modern medicine than Ayurveda. It does not strengthen Ayurveda and Ayurvedic practice. Ayurvedic research outcomes have not yet trickled down to professional use, nor do they benefit Ayurveda students or practitioners. Inadequacies in currently available regulatory laws are also proving a barrier, because many drugs and formulations developed through new research have no drug status particularly for Ayurvedic practitioners. For example, sarpagandha has a legal drug status for Ayurvedic doctors, but reserpine isolated from sarpagandha may have a drug status for allopaths, but not for Ayurvedic practitioners. Hence such research is of no value to them.

The recent paradigm shift demands research initiatives in the science of Ayurveda including exploration of more recent approaches and methodologies of therapeutic research, in order to enrich Ayurveda as it is, and to benefit Ayurvedic practitioners.^[25,26]

NEWER STRATEGIES

I am inclined to suggest that ongoing research by experts of conventional medical sciences should be continued to the benefit of their own system, but that a new approach should be adopted to research Ayurveda as a system of science and therapy, specifically within the framework of principles and philosophy of Ayurveda. Both approaches need collaboration between experts of Ayurveda, basic sciences, and medicine. However, there is a need of true teamwork between these three, which will only be possible if there is trust between team members. Such trust will only prevail if all members of the team practice truth. Thus *truth-trust-teamwork* is the vital chain in interdisciplinary research, which has been lacking, and has been the main cause of failure of otherwise well-conceived projects like Composite Drug Research Scheme (CDRS), Golden triangle project, and Science Initiatives in Ayurveda.

LIMITATIONS OF THE CONVENTIONAL APPROACH

Western medical science is fast developing, while Ayurveda is already a fully developed science of its own kind. The two have very different approaches. Conventional medicine and its research methodologies are largely based on classical Newtonian physics and related biological considerations. In contrast, Ayurvedic life sciences are based on a holistic logic now emerging in quantum science. This is why Ayurveda does not follow the organ-oriented anatomy and physiology, and adopts its own function-oriented approach through its alternative theories of *Panchamahabbut*, *Tridosha*, *Dhatu*, *Agni*, *Ama*, *Ojas*, and *Srotas*, which cannot be fully explained in terms of conventional anatomy and physiology. Hence Ayurveda research methodology has to develop its own approach.

“QUANTUM LOGIC”

Over the past 50 years, the fundamental sciences have been gradually modifying many notions in physics and bioscience, gradually shifting to quantum logic and nanoscience. In the same sequence, modern science has developed unified field theories in quantum physics, similar to the ancient Indian concept of a unified field of consciousness, in which individual human consciousness (*Atman*) and universal cosmic consciousness (*Brahman*) are realized to form a continuum. However, such a unified field of consciousness seems to involve a kind of nonphysical energy, in contrast to the unified field concept in conventional science, which merely refers to physical energy.

The entire basic bioscience of Ayurveda is based on this philosophy, and is in conflict with the conventional

reductionist approach that identifies material structures and their functions, that is, structure–function relationships. In this context, it is pertinent to quote the Cambridge Nobel laureate, physicist BD Josephson,^[27] who states “The basic premise of western science is that of an objective reality that can be reduced to a measurable uniform formula. Eastern philosophy on the other hand places emphasis on conscious experiences and subjective reality. Quantum theory poses problems for the idea of objective reality. There is difficulty in reconciling the two approaches because the reality is too complex to be reduced to an objectively identifiable formula. Subjectivity has to play an important role.”

SOME SUGGESTIONS

1. A critical literary and conceptual study of Ayurveda basic concepts viz. *Dosha, Dhatu, Mala, Agni, Ama, Ojas*, and *Srotas* as well as *Rasa-Guna-Veerya-Vipak-Prabhava*, etc. is necessary. We have to present these concepts in understandable language, suitable for creating an appropriate scientific interface for developing appropriate research methods. This part of the study will need collaboration between senior Ayurvedic and Sanskrit scholars, and scientists expert in fundamentals. The goal would be to describe “Ayurvedic biology” objectively.
2. The long-term goal in Ayurvedic research should be the “whole systems testing approach,” but in view of the high degree of system complexity, and conventional science’s limitations to handle that, I am inclined to suggest a flexible approach, where a limited degree of reductionism is permitted in order to enable modern science to probe this complexity, since reductionism is the essence of conventional science. Development of appropriate measurable markers for the above-mentioned Ayurvedic biofactors and the development of Ayurvedic clinical-sense for *tridoshic* diagnosis, implicating the important facets of *rogi-roga pariksha* and Pulse diagnosis, are important challenges which can be addressed only by a close and transparent interface between Ayurveda and contemporary science.
3. The reverse pharmacology approach to drug evaluation, together with additional therapies based on the above holistic approach, could help restore recognition of Ayurveda’s validity as a system of life and health science. In addition to the immediate goal of treatment testing for quality assurance, safety, and efficacy, the GMP Regulations should be implemented early. This task should be seriously addressed globally, and a research methodology with suitable research protocols evolved through intense interface between ancient tradition and current science.
4. Development of standard guidelines for Ayurvedic treatment of different diseases in selected target areas, including costing of individual and institutional expenditure, is another urgent need to make the system more popular and transparent, and free it from currently rampant malpractices.
5. Regulatory reforms at the level of Department of AYUSH, Central Council of Indian Medicine (CCIM), CCRAS, and amendments in the Drug and Cosmetic Act would help accelerate the development of both Ayurveda’s evidence-base and its globalization. On many occasions, faulty regulatory provisions become a real barrier even for scientific growth in multidisciplinary fields, and this should not be undermined. The extensive, currently unutilized infrastructure and human resource in the AYUSH sector needs to be mainstreamed and fruitfully utilized.^[28] Given such support, Ayurveda would have the potential to attain its past glory, to which the famous medical historian CS Welch (1968) refers in the following words: “In spite of the fact that the ancient Hindu Medicine practiced in India in the earliest times was an equally developed scientific discipline as any other contemporary system in the world, its influence on the western society was small. Hence, most of the current writings in history of medicine do not have an appropriate mention of the contributions of ancient Indian medicine.” Let us try to see that Ayurveda grows further and no more remains unnoticed.
6. Developing clinical research protocols – new clinical protocols should be developed based on classical principles of
 - *Rogi Pariksha* and
 - *Roga Pariksha*.

The protocol for *Rogi Pariksha* (examination of the patient as an individual irrespective of his disease) should be largely based on Charaka’s scheme of *Dashavidh Pariksha*, e.g., *Prakriti* etc. (CS.Vi.8) and/or Susruta’s *Dwadasha Pariksha* (SS.Su.35) supported with carefully selected biomedical markers wherever possible. The *Roga Pariksha* (examination of the disease entity/disease state) will be disease-specific and will vary from disease to disease and should be structured on the basis of the Ayurvedic concept of *Astavidha Pariksha* (*Nadi* etc.), *Srotas Pariksha*, and *Trividh Roga Marga* by developing symptom grading scales and grading scales for *Agni Bala*, *Oja Bala*, and *Manobala*, as well as *Ama* status, and integrity of *Srota* function. Attempts may be made to develop standard classification of diseases on the pattern of International Classification of Diseases (ICDs). Separate protocols should be developed to assess response to treatment given essentially comprising:

 1. Quality of life assessment (inclusive of *Sarira-Indriya-Sattva-Atma*, i.e., physical–sensorial–mental–spiritual wellbeing),

2. Graded symptom remission,
3. Evidence of *Samprapti Vighatan*/reversal of disease state.

In the majority of situations, simple subjective/objective features described in Ayurveda will be enough to draw a conclusion. However, wherever possible appropriate conventional clinical/biomedical parameters may be adopted as supporting new evidence.

CONCLUSION

There is thus a need for new strategies and new methodologies in Ayurveda research. Ongoing research using conventional methodology may bring some minor benefits to conventional modern medicine but will never result in any major breakthrough. Major inputs to Ayurveda from this kind of research are even more remote.

Hence, Ayurveda has to be studied and investigated as it is, specifically adapting an approach in tune with Ayurveda's basic principles. However, technical tools will have to be suitably adopted from modern basic and biosciences developed afresh through intense interactions between Ayurveda and counterpart sciences.

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